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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,803	07/01/2003	Eric Gervais	GOUD:031US	5065

7590 06/13/2006

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EXAMINER	
HAWES, PILI ASABI	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/611,803	GERVAIS ET AL.	
	Examiner	Art Unit	
	Pili A. Hawes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 8-19-2003, 2-19-2004, 8-1-2005, 8-26-2005
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of the Information Disclosure Statement(s) filed 08-19-2003, 2-17-2004, 8-1-2005, 8-26-2005 is acknowledged. Claims 1-9 are pending in this action. Claims 1-9 are rejected.

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 03-22-2006 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear whether the claims are intended to mean that the "at least one active ingredient" is either pyridoxine HCl alone or doxylamine succinate alone, or both drugs in combination. The claim can be interpreted two ways, either each active agent alone, or both active agents in combination. For the purposes of art rejections, the claims are interpreted to mean either active ingredient alone.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by ORIFER F Prenatal Vitamin Supplement, September 25, 1996.

ORIFER F is prenatal vitamin supplement that bears pregnancy friendly indicia on the packaging. The vitamin supplement comprises at least one active ingredient and is intended to be administered to pregnant woman as is indicated by the graphical representation of a pregnant woman on the packaging.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being obvious over ORIFER F Prenatal Vitamin Supplement for pregnant women, September 25, 1996 in view of WO 97/48384.

ORIFER F is prenatal vitamin supplement that bears pregnancy friendly indicia on the packaging. The vitamin supplement comprises at least one active ingredient and is intended to be administered to pregnant woman as is indicated by the graphical representation of a pregnant woman on the packaging.

ORIFER F does not explicitly show the pregnancy friendly indicia as being on the dosage form itself.

WO '384 teaches it is well known in the art to imprint markings or text on dosage forms such as tablets and capsules in order to minimize errors associated with administration of pharmaceuticals (page 2, lines 17-31).

Thus it would be obvious to one of ordinary skill to imprint pregnancy friendly indicia such as the one displayed on the packaging material of ORIFER F by the

method as taught by WO '384 because such indicia would indicate to pregnant woman that the vitamin is intended for them during pregnancy. One of ordinary skill in the art would be motivated to explicitly indicate that the dosage form is intended for use during pregnancy because it is well known to those of ordinary skill that some medications are not safe for pregnant women, thus a dosage form including pregnancy friendly indicia would indicate safety and improve patient compliance with taking the needed prenatal vitamin.

In the alternative interpretation of claims 5 and 9, of "the at least one active ingredient" being a combination of both pyridoxine HCl and doxylamine succinate, the following rejection is made.

Claims 5 and 9 are rejected under 35 U.S.C. 103(a) as being obvious over Gervais US 6340695 in view of ORIFER F Prenatal Vitamin Supplement for pregnant women, September 25, 1996 in view of WO 97/48384.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The reference also qualifies as prior art under 102 (a).

Gervais discloses prenatal dosage form that useful during pregnancy for treatment of nausea that comprises pyridoxine HCl and doxylamine succinate (col. 1, lines 5-10).

The combination of ORIFER F and WO '384 have been discussed above. ORIFER F discloses using pregnancy friendly indicia on the packaging of a prenatal vitamin. WO '384 teaches imprinting markings, logos, or text on solid dosage forms to minimize errors in pharmaceutical administration.

It would be obvious to one of ordinary skill in the art to imprint the pregnancy friendly indicia taught by ORIFER F on the solid dosage form taught by Gervais in the method taught by WO '384 because it would indicate to pregnant women that the product was intended for their use.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being obvious over WO 97/48384 in view of ORIFER F Prenatal Vitamin Supplement for pregnant women, September 25, 1996.

WO '384 teaches it is well known in the art to imprint markings or text on dosage forms such as tablets and capsules in order to minimize errors associated with administration of pharmaceuticals (page 2, lines 17-31).

WO '384 does not disclose pregnancy friendly indicia for prenatal vitamins.

ORIFER F is prenatal vitamin supplement that bears pregnancy friendly indicia on the packaging. The vitamin supplement comprises at least one active ingredient and is intended to be administered to pregnant woman as is indicated by the graphical representation of a pregnant woman on the packaging.

It would be obvious to one of ordinary skill in the art to use the method of imprinting logos, markings, or text onto solid dosage forms taught by WO '384 to indicate product safety or intended administration to pregnant women by using the pregnancy friendly indicia of ORIFER F. One would be motivated to put the indicia on the dosage form itself to indicate to pregnant women that the product is safe should the dosage form itself be administered, while the packaging was not accessible.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Gollamudi S. Kishore, PhD
Primary Examiner
Group 1500